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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,205	01/12/2001	Ralf Zielenski	RDID0013US	2666
23690	7590	05/13/2004	EXAMINER	
Roche Diagnostics Corporation 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/760,205	Applicant(s) ZIELENSKI, RALF	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20,22,23 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20,22,23 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed March 18, 2004 has been received and entered into the case. Claims 19, 21 and 24 – 45 are canceled; claim 54 is added; claims 18, 20, 22 – 23 and 54 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18, 20, 22 – 23 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising (a) NAD or NADP; (b) citrate/citric acid; and (c) nitrogen compounds of the claimed formula, does not reasonably provide enablement for the composition with any organic compound with a pKa value of 1.5 – 6.0. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

The specification teaches functional reagents wherein citrates are included in the composition. However, the specification fails to identify a representative number of other, functional organic compounds with a pKa value of 1.5 – 6.0, that would enable one in the art to

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effectively obtain the claimed reagent composition. Since there are innumerable organic compounds that may have a pKa of 1.5 – 6.0, it would certainly place an undue burden of experimentation on one in the art to find suitable compounds that could be effective in the claimed composition. Moreover, the specification fails to enable one in the art how to make and use the composition of the invention with any organic compound with a pKa of 1.5 – 6.0.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20, "the citric acid or citrate salt" lacks sufficient antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 18, 22 – 23 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyama et al. (US 5424204).

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Applicant claims an aqueous solution comprising (a) NAD or NADP and derivatives thereof; (b) one or more compounds selected from organic compounds or salts thereof with pKa or 1.5 – 6.0; and (c) nitrogen compounds with a specified formula; wherein pH is about 2.0 – 4.0. The nitrogen compound is a hydroxylamine derivative or salt thereof and is in the amount of 2 – 300 mM. Applicant alternatively claims the composition wherein it remains unchanged for 15 months at about 2 – 8C.

Aoyama teaches reagent compositions comprising hydroxylamines of the claimed formula (abstract, col.2-3), citrate buffers and NAD or NADP (col.6), with a pH of 3 – 11.

Although Aoyama does not specifically disclose a composition comprising the claimed components, one in the art is able to “at once envisage” the specific combination within the generic composition.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 18, 20, 22 – 23 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama.

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Applicant claims an aqueous solution comprising (a) NAD or NADP and derivatives thereof; (b) one or more compounds selected from organic compounds or salts thereof with pKa or 1.5 – 6.0; and (c) nitrogen compounds with a specified formula; wherein pH is about 2.0 – 4.0. The nitrogen compound is a hydroxylamine derivative or salt thereof and is in the amount of 2 – 300 mM. Applicant alternatively claims the composition wherein it remains unchanged for 15 months at about 2 – 8C.

Aoyama teaches reagent compositions comprising hydroxylamines of the claimed formula (abstract, col.2-3), citrate buffers and NAD or NADP (col.6), with a pH of 3 – 11.

Although Aoyama does not specifically disclose a composition comprising the claimed components, one in the art is able to “at once envisage” the specific combination within the generic composition.

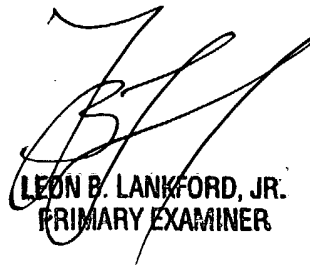
Aoyama does not teach the composition comprising 5 – 200 mM citrate. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amount of citrate buffers as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of citrate buffer in the composition of Aoyama, with a reasonable expectation for successfully obtaining the effective reagent composition of Aoyama.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
May 10, 2004.



LEON B. LANKFORD, JR.
PRIMARY EXAMINER